UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

LEAH ROYCE HINES,

Plaintiff,

v. Civil Action No. 2:04-0690

WYETH, d/b/a Wyeth, Inc.;
WYETH PHARMACEUTICALS, INC.;
and PHARMACIA & UPJOHN COMPANY,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending is defendants' motion to exclude the expert testimony of Drs. Matthew Hollon and Adriane Fugh-Berman (Doc. No. 267), filed May 27, 2011.[1]

Plaintiff having since advised that she will not be calling Dr. Fugh-Berman to testify at trial, the court accordingly ORDERS that defendants' request to exclude her testimony be, and it hereby is, denied as moot.

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[1] At a pretrial conference on June 17, 2011, the court conferred with counsel regarding the necessity of an evidentiary hearing on the various Daubert motions currently pending before the court. (See Doc. No. 343). The parties made clear that such a hearing was not necessary. Defendants have, however, requested oral argument on the motions. Inasmuch as the parties' briefs and supporting exhibits adequately present the issues ripe for adjudication, the court finds that oral argument would not aid the decisional process and accordingly denies defendants' request for oral argument as to the motion discussed herein.

I. Background

This is a pharmaceutical products liability action in which plaintiff Leah Royce Hines alleges that she developed breast cancer as a result of ingesting hormone replacement therapy ("HRT") drugs manufactured by defendants. HRT here consists of two medications, estrogen and progestin ("E+P"), that are commonly prescribed in combination to treat menopausal symptoms.

This action concerns three HRT drugs: Premarin, Prempro, and Provera. Defendant Wyeth, LLC ("Wyeth") manufactured Premarin, an estrogen drug, and Prempro, a combination estrogen and progestin drug. Defendant Pharmacia & Upjohn Company ("Upjohn") manufactured and distributed Provera, a progestin drug. The generic name for Provera is medroxyprogesterone acetate ("MPA").

Plaintiff's physician prescribed HRT drugs to treat her menopausal symptoms from approximately July 1994 to April 1999. She was diagnosed with breast cancer in July 1999, and thereafter instituted this action on July 7, 2004, invoking the court's

diversity jurisdiction.[2] Her complaint asserts claims against defendants for negligence, strict liability (design defect and failure to warn), and breach of implied warranty. Defendants now seek to exclude the testimony of Dr. Matthew Hollon, plaintiff's proposed expert witness on defendants' promotional techniques.

II. Governing Standard

The admission of expert testimony is governed by Federal Rule of Evidence 702 and the Supreme Court's decision in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Under Rule 702 and Daubert, expert testimony must satisfy a two-prong test: (1) the testimony must concern "scientific, technical, or other specialized knowledge"; and (2) it must "aid the jury or other trier of fact to understand or resolve a fact at issue." Westberry v. Gislaved Gummi AB, 178 F.3d 257 (4th Cir. 1999) (citing Daubert, 509 U.S. at 592); Fed. R. Evid. 702. "The first prong of this inquiry necessitates an examination of whether the reasoning or methodology underlying the expert's proffered opinion is reliable -- that is, whether it

[2] The case was transferred to multidistrict litigation in the United States District Court for the Eastern District of Arkansas on October 26, 2004. Over five years later, on April 13, 2010, it was remanded to this court for the completion of discovery, pretrial activity, and trial.

is supported by adequate validation to render it trustworthy." Id. "The second prong of the inquiry requires an analysis of whether the opinion is relevant to the facts at issue." Id. Thus, an expert's testimony is admissible under Rule 702 if it "rests on a reliable foundation and is relevant." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999).

As to the reliability prong, the Court in Daubert announced a non-exhaustive list of factors to guide the trial judge's inquiry, including "(1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing Daubert, 509 U.S. at 592-94).

As to the relevancy prong, "the expert's proffered scientific testimony must be sufficiently tied to the facts of the case that it will be of assistance to the factfinder in resolving a disputed fact." Bourne ex rel. Bourne v. E.I. Dupont de Nemours & Co., 189 F. Supp. 2d 482, 495 (S.D. W. Va. 2002). "That is, there must be a 'valid scientific connection to the

pertinent inquiry' before the testimony is admissible." Id. (quoting Daubert, 509 U.S. at 591-92).

Our court of appeals has summarized the overarching duties of a trial court in resolving Daubert motions as follows:

> A district court considering the admissibility of expert testimony exercises a gate keeping function to assess whether the proffered evidence is sufficiently reliable and relevant . . . The inquiry to be undertaken by the district court is "a flexible one" focusing on the "principles and methodology" employed by the expert, not on the conclusions reached. Daubert, 509 U.S. at 594-95 . . . In making its initial determination of whether proffered testimony is sufficiently reliable, the court has broad latitude to consider whatever factors bearing on validity that the court finds to be useful . . . The court, however, should be conscious of two guiding, and sometimes competing, principles. On the one hand, the court should be mindful that Rule 702 was intended to liberalize the introduction of relevant expert evidence. . . . [T]he court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct . . . As with all other admissible evidence, expert testimony is subject to being tested by "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." Daubert, 509 U.S. at 596 . . . On the other hand, the court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to "be both powerful and quite misleading." Id. at 595 . . . [G]iven the potential persuasiveness of expert testimony, proffered evidence that has a greater potential to mislead than to enlighten should be excluded.

Westberry, 178 F.3d at 261 (some citations and footnotes omitted). Ultimately, "[t]he proponent of the [expert] testimony must establish its admissibility by a preponderance of proof."

Cooper, 259 F.3d at 199.

III. Analysis

Plaintiff seeks to admit the testimony of Dr. Matthew Hollon to demonstrate that defendants failed to meet the reasonable standard of care in promoting their drugs. According to his expert report, Dr. Hollon, a board certified physician of internal medicine, opines that defendants:

> 2. [E]xpand[ed] the perception that hormone therapy is appropriate for every menopausal woman and utiliz[ed] aggressive integrated mark[et]ing tactics targeting physicians and patients together as the "consumer" such that physicians would prescribe hormone supplementation in the face of patient requests.
>
> 3. Persuaded the medical community and the public that healthy, asymptomatic menopausal women should take hormones for an ever expanding list of symptoms by manufacturing data, purchasing professional opinions, and utilizing the entire catalogue of possible promotional activities based on often misleading and unbalanced marketing schemes that over zealously relied on purported but often unfounded benefits.
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> 4. Started inappropriately and continued over several decades a . . . marketing strategy without scientific support for long-term use eventually ignoring sound epidemiologic principles by unreasonably pushing hormone supplementation for population prevention in all menopausal women beginning early in menopause when these women, on average, were more likely to suffer harm than realize the minimal benefit.
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> 5. Systematically ignored or minimized unfavorable

> scientific evidence and, thus, failed to adequately warn physicians and patients of the risks of hormone supplementation.

(Defs.' Mot. to Exclude Test. of Dr. Hollon, Ex. 8, Hollon Report ("Hollon Rep.") at 3). In short, Dr. Hollon contends that defendants irresponsibly used promotional techniques (for example, marketing their HRT drugs to healthy, asymptomatic menopausal women), and minimized or ignored scientific evidence establishing a link between their drugs and breast cancer. Dr. Hollon opines that these tactics directly influenced physicians' prescribing practices, such that "many women who needed [HRT drugs] perhaps only for short-term relief were kept on [them] for years." (Hollon Rep. at 87).

Defendants contend that Dr. Hollon's proposed testimony is irrelevant. First, they emphasize that Dr. Hollon has "no knowledge whether plaintiff['s] physicians relied upon any alleged misleading marketing by [defendants] in prescribing her HT or whether [plaintiff] relied upon any such marketing in deciding to take HT." (Mem. Supp. Defs.' Mot. to Exclude at 2). Indeed, as defendants emphasize, Dr. Hollon's report does not even mention plaintiff or her prescribing physicians. Second, defendants note that plaintiff "testified that she did not rely on marketing materials" and that "there is nothing in the record

to suggest that [her] physicians relied on them either." (Id.). Accordingly, defendants maintain that Dr. Hollon's proposed testimony concerning their marketing and promotional strategy would be of no assistance to the jury.

In response, plaintiff acknowledges that Dr. Hollon is not a "case specific expert." (Pl.'s Opp. at 2). Rather, according to plaintiff, "he is a generic liability expert with opinions about [defendants'] conduct and its impact on drug safety." (Id. at 3). Plaintiff contends that Dr. Hollon's testimony would "educate the jury about the different ways [defendants] can provide information to doctors about [their] drugs and how [defendants] chose to use those avenues to minimize the breast cancer risk." (Id.). Plaintiff thus concludes that Dr. Hollon's testimony is relevant and admissible under Daubert.

Plaintiff's contention misses the mark. Although Dr. Hollon has a knowledge of pharmaceutical marketing that is well beyond a juror's common understanding, his testimony would aid the jury only if defendants' marketing strategy were somehow relevant to the issues before it. See, e.g., Torkie-Tork v. Wyeth, No. 1:04-cv-945 (E.D. Va. Nov. 16, 2010) (observing that Dr. Hollon's testimony concerning defendants' marketing tactics would amount to "a waste of time" unless plaintiff demonstrates

actual reliance); In re Prempro Prods. Liab. Litig., MDL Docket No. 4:03cv1507 (E.D. Ark. Aug. 21, 2006) (permitting Dr. Hollon to testify only to "issues that are directly linked to Plaintiff"). For instance, Dr. Hollon's conclusion -- that "most of these women would not have sought out this drug and many women would have avoided the harms attendant to hormone therapy" but for defendants' marketing strategy -- is wholly irrelevant if plaintiff cannot demonstrate that she personally would have avoided harm had the defendants marketed their drugs more appropriately. (Dr. Hollon Rep. at 87 (emphasis added)). Yet, nowhere in the record is there evidence suggesting that plaintiff or her prescribing physicians were influenced by defendants' promotional conduct. It follows that Dr. Hollon's testimony concerning defendants' marketing strategy is irrelevant to plaintiff's case and therefore inadmissable.[3]

[3] In her response to defendants' motion, plaintiff appears to suggest that Dr. Hollon is prepared to testify to issues other than defendants' promotional strategy, including testimony "that there is a particular added obligation [on the part of pharmaceutical drug manufacturers] to study drugs intended for older patients because of the medical susceptibilities present in the elderly." (Pl.'s Opp. at 3). Dr. Hollon's report, however, appears to be devoted entirely to the appropriateness of defendants' marketing tactics. Inasmuch as the court is unable to discern any other relevant topic in the report, Dr. Hollon's testimony is precluded in its entirety.

IV. Conclusion

Pursuant to the foregoing analysis, it is ORDERED that defendants' motion to exclude the testimony of Dr. Hollon be, and it hereby is, granted.

The Clerk is directed to forward copies of this written opinion and order to all counsel of record.

DATED: July 8, 2011

John T. Copenhaver, Jr.
United States District Judge